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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,331	09/17/2004	Christopher Luckhurst	06275-416US1	9145
26164 7590 02/07/2008 FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER CHUNG, SUSANNAH LEE	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/508,331	Applicant(s) LUCKHURST ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/17/04 and 8/18/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-9 and 12 are pending in the instant application. Claims 10-11 are canceled by preliminary amendment.

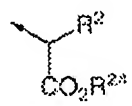
Priority

This application is a 371 of PCT/SE03/00443, filed 3/17/2003.

Information Disclosure Statement

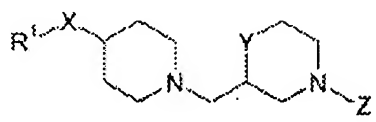
The information disclosure statement(s) (IDS), filed on 8/18/2006 and 9/27/2004 has/have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

Applicant's election without traverse of the group that encompasses claims 1-7 and 9 drawn to compounds of formula (I), wherein R¹ is aryl, X is O, Y is CH₂ and Z is  is acknowledged. Rejoinder of a method of using or making will be considered if there is allowable subject matter.

Scope of the Elected Invention

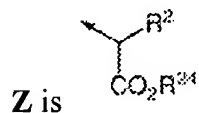
Claims 1-9 and 12 are pending in this application. The scope of the elected subject matter that will be examined and searched is as follows:

Compounds of formula (I), , depicted in claim 1, page 3, wherein:

R¹ is aryl,

X is O,

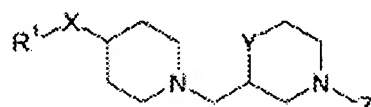
Y is CH₂, and



Scope of Withdrawn Subject Matter

Claims 3, 8 and 12 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the withdrawn subject matter that will not be examined and searched is as follows:

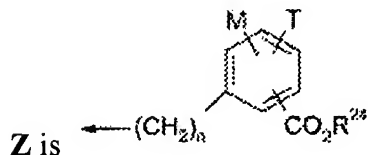


Compounds of formula (I), , depicted in claim 1, page 3,

wherein:

X is CH₂, C(O), S, S(O), S(O)₂, or NR₃,

Y is O, and



Obviousness Double Patenting

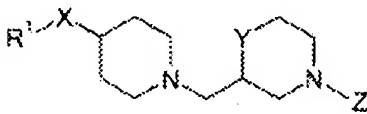
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

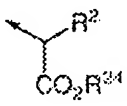
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 and 9 of copending Application No. 10/528,477. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

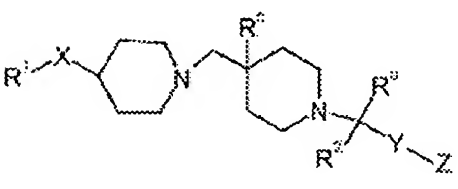
Applicants instant elected invention discloses the compounds and compositions of

formula (I), , depicted in claims 1-7 and 9, wherein R1 is aryl, X

is O, Y is CH2 and Z is  preferably.

Determination of the scope and content of the co-pending application

Co-pending application No. 10/528,477 claims the compound of formula (I),

, wherein R1 is aryl, X is O, Rc is hydrogen, R2 or Ra is aryl, Y is a bond, Z is CO2Rb, and Rb is hydrogen, alkyl, or aryl.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between co-pending application no. 10/528,477 and the instant application is that they are positional isomers of one another.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed compounds prima facie obvious over the co-pending applications because a skilled artisan would deem positional isomers to be obvious. Adjacent homologues and structural isomers are generally so structurally similar that “without more” such structural similarity could give rise to prima facie obviousness. In re Wilder, 563 F.2d 457, 195 USPQ 426. The instant claims are positional isomers of the copending because they have the same radical on a different position, i.e. the instant claims are

drawn to 3-piperidinyl compounds, while the copending application is drawn to 4-piperidinyl compounds.

One of ordinary skill in the art would be motivated to optimize known compounds with the expectation that structurally similar compounds, i.e. isomers, would have similar properties, i.e. in treating chemokine mediated diseases. Optimization is routine practice in the pharmaceutical arts and is not patentably distinct.

In addition, positional isomerism has been used as a tool to obtain new and useful drugs. In re Grabiak, 226 USPQ 870. Given the preferred embodiments and the specific embodiments listed in the claims, one of ordinary skill in the art would be motivated to produce the species common to the applications. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Both the instantly claimed compounds and the compounds of the copending applications are used for treating chemokine mediated disease states. Although, the conflicting claims are not identical, they are not patentably distinct from each other. Therefore, one skilled in the art would have found the positional isomer obvious when faced with the copending applications because the compounds are used for the same pharmacological use so one skilled in the art would expect similar properties and results. A timely filed terminal disclaimer will overcome this rejection.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "solvate" of the compound of Claims 1 and 9 are not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1 and 9.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 9 are indefinite for the reasons set forth above under 35 U.S.C. 112, first paragraph. Claims 1 and 9 drawn to the "solvate" of compounds in Claim 1. However, the "solvate" of the compounds of Claims 1 and 9 are not defined in the claims so as to know the metes and bounds of the claims. Therefore, the claim is indefinite.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Application/Control Number:
10/508,331
Art Unit: 1626

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLC

**KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER**

Kamal Saeed, PhD.
Primary Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 4 February 2008